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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,010	12/03/2003	T. Scott Pinkerton	P05574US01	5502

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/727,010

Applicant(s)

PINKERTON ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-40 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 03 December 0203 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed on 1 June 2005.
2. The objection to the specification is withdrawn in view of Applicant's amendment.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. Claims 1, 2, 5, 13, 14 and 17 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Phillips *et al* (Proc. Natl. Acad. Sci. USA 1990, 87:8155-8159). This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 March 2005. Applicant's arguments filed 1 June 2005 have been fully considered but they are not persuasive.

Applicants argue that OPH activity was measured, but not used to select transformed cells, and that the use of OPH as a selectable marker is not disclosed; use of OPH in attempts to keep an insect alive when exposed to organophosphate is the aim (page 10, 2nd and 3rd paragraph of the Remarks). Applicants' arguments directed to an intended use of the claimed method are not found to be persuasive. Applicant uses open claim language and the prior art discloses all of the claim limitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the

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intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicants argue that the reference does not disclose a method for determining whether a cell has incorporated and expressed a polynucleotide by introducing a construct comprising a polynucleotide encoding an enzyme having OPH activity, contacting the cell with an organophosphate "such that if the cell does not contain the construct and an enzyme having organophosphate hydrolase activity is not thereby produced, the cell growth is inhibited," and thereby determining whether the cell has incorporated the polynucleotide. Applicants argue that inhibition of cell growth used to select for transformed cells is not disclosed in Phillips, and thus claims 1, 13 and dependent claims are not disclosed or anticipated by Phillips. Applicants argue that claim 13 further recites that construct comprises the OPH encoding nucleotide and a first polynucleotide, and determining whether the cell has incorporated first polynucleotide, the heat shock sequences in Phillips *et al.* are used to determine induction of the OPH gene, not to determine whether the heat shock gene was transformed in to the cells (page 11, 2nd paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given supra. Applicants' arguments directed to claim 13 is not persuasive because induction of the OPH gene by the heat shock protein demonstrates the incorporation of the heat shock protein, required to induce expression of the OPH gene, hence the limitations of claim 13 are disclosed by Phillips *et al.*

Claim Rejections - 35 USC § 103

5. Claims 1-40 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Barrett (U.S. Patent 6,380,465, filed 11 July 1999) in view of Jilka (WO 99/53037, published 21 October 1999) and Hood *et al* (WO 01/96543 A2, published 20 December 2001). This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 March 2005. Applicant's arguments filed 1 June 2005 have been fully considered but they are not persuasive.

Applicants argue that Barrett does not teach a nucleotide sequence encoding organophosphate hydrolase and that the patent is instead directed to P450 enzyme encoding sequences, which enzyme can metabolize the herbicides and insecticides. Applicants argue that one cannot conclude that the ability of P450 enzymes to metabolize organophosphates demonstrates that an entirely different gene group, those encoding organophosphate hydrolases, will not only metabolize organophosphates, but that the property can be used to produce a selectable or scorable marker (page 12, 3rd paragraph of the Remarks). These arguments are not found to be persuasive because Barrett teaches that one of ordinary skill in the art would have been motivated to identify and use polynucleotides that confer resistance to organophosphate herbicides to a plant transformed therewith. Barrett teaches that it was obvious to one of ordinary skill in the art to determine the production of metabolites by using detection methods well known in the art (column 6, 4th paragraph).

Applicants argue that the fact one can test for potential protection does not suggest or show with any predictability that a specific protein produced by a gene not

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only will protect a cell from harmful affects when exposed to a proposed compound, but can also be used as a selectable or screenable marker, nor is the invention as claimed suggested by demonstration that nucleotide sequences encoding OPH can be expressed in plants (page 13 of the Remarks). These arguments are not found to be persuasive because the teachings of Barrett are cited to demonstrate that one of ordinary skill in the art at the time of Applicants' invention would have been motivated to use polynucleotides that metabolize organophosphate herbicides, and that such polynucleotides could be used as selection markers.

Applicants argue that the references do not suggest that OPH genes can be used as a scorable marker, where destruction of the non-transformed cells is not required; instead, hydrolysis of the organophosphate is detected, as recited in claims 7, 19 and 33, and dependent claims (page 14, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Hood *et al* teach that cleavage of paraoxon yields p-Nitrophenol, which can be measured spectrophotometrically at 400nm. In addition, one of ordinary skill in the art at the time of Applicants' invention would have know this characteristic of paraoxon, and that with sufficient production of the metabolite p-Nitrophenol, the solution in which the transformed cell is incubated, would become a yellow color indicating successful incorporation and expression of the polynucleotide. There is nothing in the instant claims that would lead to a teaching of unexpected results.

Applicants argue that the protein of a gene successfully expressed in a plant can typically be detected; but its use as a scorable marker requires more and that to qualify

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as a scorable/screenable marker the nucleic acid must not only express the protein in plants, but the substrate added must be able to penetrate the cell, and be hydrolyzed such that it can be readily detected and here can be visually observed or measured without the necessity of destroying the cell or extracting the resultant hydrolysis products or enzyme from the cell. Applicant further argues that to qualify as a scorable marker the product produced by hydrolysis must not be lethal to the cell and that a marker that is both selectable and scorable is both valuable and unexpected (paragraph spanning pages 14-15 of the Remarks). These arguments are not found to be persuasive. It would have been readily apparent to one of ordinary skill in the art at the time of the instant invention that paraoxon can readily penetrate a plant cell. Jilka *et al* teach that polynucleotides encoding organophosphorous hydrolase can be expressed in plants and that these polynucleotides can be optimized for expression in corn. Jilka *et al* also teach that the polynucleotide can be expressed in sufficient quantity to decontaminate soil at claim 25, which would also require that the substrate penetrate the cell.

Applicants argue that the references do not suggest use of the OPH gene as a selectable or scorable marker, and do not teach a method of determining whether a cell has incorporated and expressed a polynucleotide by introducing the OPH in to the cell, contacting the cell with organophosphate, and either determining if the cell has incorporated the polynucleotide by observing cell growth inhibition or detecting hydrolysis of the organophosphate (page 15, 2nd paragraph of the Remarks). This

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argument is not found to be persuasive for the reasons given supra. *Jilka et al* teaches that organophosphate herbicides were known in the art (see page 1).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (571) 272-0745. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
16 August 2005

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9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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